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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,577	05/02/2005	Claire Raynal-Olive	P-6012	4521
7590 02/21/2007			EXAMINER	
David W Highet			GEHMAN, BRYON P	
Becton Dickinson & Company				
1 Becton Drive MC 110			ART UNIT	
Franklin Lakes, NJ 07417			PAPER NUMBER	
			3728	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	02/21/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/511,577

Applicant(s)

RAYNAL-OLIVE ET AL.

Examiner

Bryon P. Gehman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 1-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because the title in bold letters is not necessary, in lines 6-7, "said piece" is improper, and the extraneous "Figure 1" is also unnecessary. Correction is required. See MPEP § 608.01(b).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, line 4, "the latter" is indefinite as to which antecedent is being referred to. In line 6, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation following the phrase is part of the

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claimed invention. See MPEP § 2173.05(d). See also lines 9 and 14 of the claim, and further see claim 11, lines 3 and 4, claim 14, lines 5 and 10 and claim 17, line 3.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1, 11, 14 and 17 recite the broad recitation "decontamination gas", and each claim also recites "hydrogen vapors" which is the narrower statement of the range/limitation.

In claim 1, lines 9-10, "the said flexible piece" lacks antecedent basis or is inconsistent with line 8. See also line 11, "said piece" and claim 4, line 3, claim 5, line 2, claim 6, line 2, claim 7, lines 2, 3 and 4, claim 9, lines 2 and 3, claim 15, line 2 and claim 16, line 2. In lines 13 and 14-15, "the window" lacks antecedent basis or is inconsistent with line 7. See also claim 6, line 3, and claim 7, lines 2-3, 3 and 4.

In claim 2, line 4, "these" is indefinite which antecedent is being referred to. Also in line 4, "combinations thereof" is indefinite which antecedent is being referred to.

In claim 7, line 4, "this window" is indefinite, as it pertains to one particular window, when applicants' have originally defined "at least one window". This renders "its" in line 5 indefinite.

In claim 8, line 2, "several windows" is indefinite as the relationship of these windows to the previously defined, and if it refers to the "at least one window", then it is double recitation, as "several" windows are covered by "at least one window".

In claim 9, line 2, the "several windows" is indefinite as to its relationship to the window or windows already defined. Reference numerals may not be used to distinguish claim language. In line 3, "with overlap" is indefinite as to what is being defined, as the present phrase is obscure.

In claim 10, line 2, "several flexible pieces" is indefinite as to their relationship to the previously defined "at least one flexible piece". Reference numerals may not be used to distinguish claim language. In lines 3-4, "each flexible piece covers, with an overlap, the window facing which it is fixed" does not make a coherent statement of arrangement. "Window facing" lacks antecedent basis.

In claim 12, line 2, "the said layer" lacks antecedent basis or is inconsistent with claim 11, line 2. Also in line 2, "has shape and size" is ungrammatical. In line 3, "it this position" does not make sense. In line 3, "the objects contained in the packaging" lacks antecedent basis for such actually occurring. See also claim 13, lines 2-3.

In claim 13, line 2, "said layer or at least one of said layers are" is inconsistent with claim 11, line 2 and should be --said at least one layer is--. In line 4, "that purpose" is indefinite, as no purpose per se has been so defined. In line 4, "this box" is indefinite, as "this..." indicates one box of many, but many have not been defined. It should just be --the box--.

In claim 14, the entire claim comprises double recitation, as the reference to claim 1 provides antecedent for all the elements already recited to comprise the packaging of claim 1. Accordingly, the elements numbered 4, 6, 7, 8, 3 and 16 should be referred to as previously defined in claim 1, which is referenced. Accordingly, in line 4, "forming a cover sheet" should be --forming the cover sheet--, and the further recitation of its permeability with regard to hydrogen peroxide vapors is double recitation, as such was already set forth in parent claim 1. This pertains to the repeated recitation with regard to elements 4, 6, 7, 8, 3 and 16 found in claim 14. In line 6, "this cover sheet" should be --the cover sheet--. In lines 7, 8 and 12, a singular window is inconsistent with line 5-6 and should be --said at least one window-- in each instance. In line 8, "this material" should be --said material--. In line 13, "the objects" have not been positively defined in claim 1, but are merely inferred, so line 13 should read --placing objects (2) in the box (3)--. In line 14, "this box" should be --the box--.

In claim 17, line 1, "The use" lacks antecedent basis and should be --A use--. In line 2, "this packaging" should be --the packaging--.

In claim 18, line 1, "The use" lacks antecedent basis and should be --A use--. In line 2, "syringe components, particularly syringe bodies" is again a broader range in

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conjunction with a narrower range, which is indefinite. In line 3, the two alternatives should be preceded by --one of--.

5. Claims 1-19 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Each pertains to a package that comprises material and structure that render the package selectively sterilizable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryon P. Gehman whose telephone number is (571) 272-4555. The examiner can normally be reached on Tuesday through Thursday from 7:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bryon P. Gehman
Primary Examiner
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BPG